Individual Safety Report
3235066-8-00-01

McNeil Consumer Healthcare
Neil Consumer Healthcare
Vashington, PA 19034-2099

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APR 0 8 1999
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Approved by FDA on 11/15/91

UF/Dist report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
614048	or 37 yrs	( )female	unk lbs
In confidence	Date of birth: [redacted]	(X)male	or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
(X) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr): 3/4/95

4. Date of this report (mo/day/yr): 04/05/99

5. Describe event or problem

Notification via litigation of case summaries provided by physician/co-author of literature report (N Engl J Med 1997;337:1112-7). Medical records provided of pts hospitalized for acetaminophen ingestion b/t 1/1/92 & 4/30/95. Med records indicate a 37 yo w/ h/o multi-drug abuse presented to hosp on 3/3/95 w/ 3 day h/o FEVER, CHILLS, HEADACHE, assoc with RUQ and mid epigastric pain (ABDOMINAL PAIN). One to two days PTA, developed N/V, ANOREXIA/malaise, progressing to coffee grounds x5. Pt also reported dark urine (URINE ABNORMALITY). Pt had been drinking 2 fifths etoh/wk & beer for 3 months PTA. Pt denied excessive TYLENOL use. He ran out of TYLENOL #4 one month ago-may have taken some Extra Strength TYLENOL-he was not sure. Pt does report chronic NSAID use but unable to quantitate amt. Liver US revealed HEPATITIS & serologies found infectious HBV & HCV. Tx included FFP, ZANTAC®, & MUCOMYST®. EGD revealed esophagitis, duodenitis, hiatal hernia & portal HTN gastropathy. Pt placed on omeprazole. (See Sec C10)

6. Relevant tests/laboratory data, including dates

3/3/95 (2350)AST=10530,ALT=6360,AP=217,Tbili=5.4,TP=6.7,Alb=3.6,GGT=503;3/4/95(0700)pH=7.47,PCO2=40,PO2=69,HCO3=29,O2Sat=94;(1140)PT=23.0,PTT=39.7,APAP=less than 1,salic=less than1 cocaine & metab;trimethoprim detected in urine, (See Sec B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

5/5/87 admitted to hosp s/p OD on 30 TYLENOL® #3 & 15 TRANXENE®; previous suicide attempts, gastritis, hiatal hernia, asthma, scoliosis, depression, h/o drug abuse: cocaine, heroin, hx of addiction to TYLENOL® #3 & #4, IVDA (cocaine last used 2 weeks ago), ETOH (last drink 3/3/95) (Sec B6 cont)etoh=(-);HBsAG,a-HBc,a-HBc IgM,a-HCV (reactive)

C. Suspect medication(s)

1. Name (give labeled strength & unit & if known)

#1 possibly Extra Strength TYLENOL®
#2 unk NSAID possibly ibuprofen (See also Sect C10)

2. Dose, frequency & route used

#1 may have taken some
#2 unknown

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 unknown dates or duration
#2 unknown

4. Diagnosis for use (indication)

#1 pain
#2 back pain

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

6. Lot # (if known)

#1 unknown
#2 unknown

7. Exp. date (if known)

#1 unknown
#2 unknown

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

THEO-DUR®,PROVENTIL®,SOMA®,BACTRIM®DS;(Sec C1 cont):TYLENOL® #4(last dose 3-4 wks prior);(Sec B5 cont):Pt d/c'd 3/11/95 clinically improved w/LFT's beginning to normalize. Prin dx: UGI bleed (HEMORRHAGE GI) & acute viral hepatitis (HBV-HCV).

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

APR 0 9 1999

RECEIVED
APR 0 8 1999
ADVERSE EVENT REPORTING SYSTEM

2. Phone number: 215-273-7820

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
( ) consumer
(X) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 03/29/99

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

CHILLS FEVER
HEADACHE
PAIN ABDOMINAL
NAUSEA VOMIT
ANOREXIA
URINE ABNORMAL
HEPATITIS
HEMORRHAGE GI

9. Mfr. report number: 1153613A

E. Initial reporter

1. Name, address & phone #

[redacted] MD &
[redacted] Medical Ctr
[redacted] Boulevard
[redacted]

2. Health professional? (X) Yes ( ) No

3. Occupation: physician

4. Initial reporter also sent report to FDA: ( ) Yes ( ) No (X) Unk

FDA
Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.